IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Jeremy MARSHALL et al. Conf. 8915

Application No. 10/506,472 Group 3767

Filed April 6, 2005 Examiner Andrew Gilbert

MULTI-SPRING SUPPORT FOR NEEDLE SYRINGES

REPLY BRIEF

MAY IT PLEASE YOUR HONORS:

This is a reply to the Examiner's Answer of January 12, 2010.

STATUS OF CLAIMS

Claims 1-8 have been canceled. Claims 9-13 are pending, from which this appeal is taken.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The two grounds of rejection to be reviewed on appeal are as follows:

1. The rejection of claims 9-13 under 35 USC §112, second paragraph as indefinite, which was withdrawn in the Examiner's Answer; and

2. The rejection of claims 9-13 under 35 USC §102(b) as being anticipated by BERGENS et al., U.S. Patent 6,270,479.

ARGUMENT

In short, the Office has misunderstood the structure and function of at least the spring 156 of BERGENS et al. at least to the extent that the anticipation rejection cannot stand.

Now consider BERGENS et al.

BERGENS et al. disclose two types of damping; one for autopenetration movement (i.e. movement of the syringe forwards in the housing to insert the needle into the injection site) and one for autoinjection movement (i.e. movement of the syringe plunger to expel a dose). Figures 1A-1D of BERGENS et al. are reproduced below.

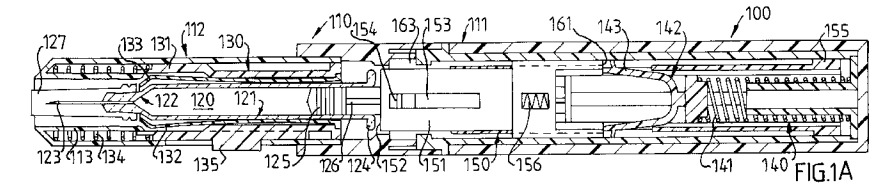

FIG.1A

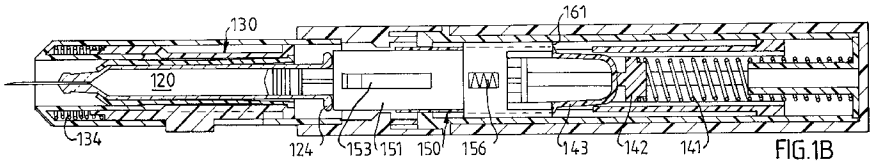

FIG.1B

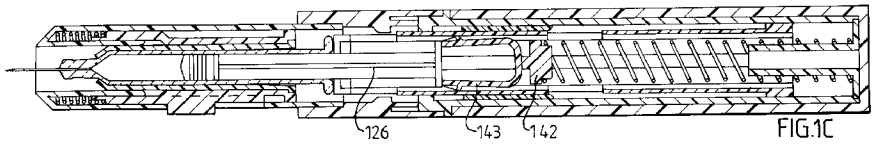

FIG.1C

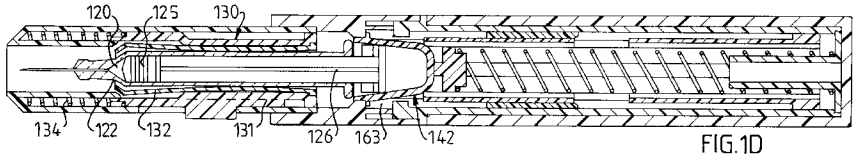

FIG.1D

The embodiment of Figures 1A to 1D relied upon by the Examiner is described in the list of Figures and column 11 lines

44 to 47 as having '*…a common drive for autopenetration and autoinjection and having elastic dampers…*', but the ***only*** damping action described in relation to this embodiment is in the two paragraphs starting at column 11 line 47 to column 13 line 20. The reference is to a damping spring 156 which urges the two components 151, 153 of the penetration head assembly 150 apart. Although not explicitly stated, it is clear that this provides damping of the autopenetration movement only. (Strictly speaking of course a simple spring will only provide shock absorption rather than true damping). During the autopenetration movement, the load path passes from spring 141 ⇨ injection head 142 ⇨ plunger guide 153 (column 12 line 66) ⇨ spring 156 ⇨ syringe plunger part 151 ⇨ syringe finger grip 154.

Also, the relative telescoping movement of the syringe plunger guide 153 into the syringe plunger part 151, exposes the tapering surfaces 161 ('*become active*') see column 12 lines 47 to 50. Once exposed, the tapering surfaces 161 compress or cam the legs 143 of the injection head 142 towards each other so that the injection head disengages from slots on the plunger guide to move forwardly to land on the container plunger 126 (more conventionally referred to as the '*syringe plunger*').

In BERGENS et al, note that when the penetration head is at its forward position, the spring 156 ***must*** have been compressed otherwise the plunger guide 153 will not shift forwardly relative to the syringe plunger 151 to expose the

tapering surfaces 161 to initiate the autoinjection movement. As movement of the spring 156 to its compressed state is a prerequisite for the initiation of the autoinjection phase and proper operation of the device, BERGENS et al does not provide an arrangement in which, '….*the first spring, as it fully expands, will then compress the second spring to urge the plunger forward and thereby move the piston and expel the dose*…'. The spring 156 has already been compressed by the time the injection head 142 lands on the container plunger 126 and so BERGENS et al cannot fulfil the requirement that the first spring expands as the second spring is compressed simultaneously to expel a dose. Note that the word 'compress' is used in the ordinary sense of making something smaller by the application of pressure; it therefore requires active contraction movement of the second spring.

Beyond this, note that BERGENS et al relies upon a '*control system*' to sequence operations, which includes the penetration head assembly 150 made up of the syringe plunger part 151 and the rear plunger guide 153 and the spring 156, which assembly cooperates with the injection head 142. Initially the thrust of the spring 141 is applied by the penetration head assembly 150 to the finger grip 124 of the syringe, during the autopenetration phase. As it reaches the forward most position, the penetration head assembly 150 operates so that the rear plunger guide 153 moves forwardly to cause the legs 143 of the injection head 142 to be unlatched from their engagement in the

slot on the plunger guide 153, with the result that the injection head lands on the container plunger 126. In other words, BERGENS et al. require an intricate mechanical sequencing mechanism which uses telescoping parts, a spring 156, and the tapered surfaces 161 etc to ensure that the autopenetration phase is complete before the autoinjection phase is initiated. In contrast to this, in the present invention, sequencing is achieved by an arrangement of first and second springs acting on the syringe plunger without any form of mechanical unlatching mechanism.

Response to Examiner's Arguments

In lines 17 to 19 on page 3, the Examiner argues that spring 156 acts in compression between said plunger (earlier identified as plunger 126) and the syringe. The second spring 156 does not act in compression between the plunger 126 and the syringe 120. Instead, the spring 156 is mounted between the syringe plunger guide 153 and the syringe plunger part 151 and is compressed by the syringe plunger guide 153 moving forwards relative to the syringe plunger part. Note particularly that in BERGENS et al. the item referred to variously as the '*syringe plunger part 151*', '*the syringe plunger 151*' etc. is a ***sleeve*** (column 12 line 24) and is a part of the penetration head assembly 150. It is ***not*** the same as the item that would usually be termed the syringe plunger, namely item 126 referred to in BERGENS variously as '*plunger*', '*syringe piston*', 'container plunger' and 'rear plunger'. Following release of the injection

head from the syringe plunger guide items 151, 153, 156 are not in the load path made up of the spring 141 ⇨ plunger 126 ⇨ piston 125.

On page 4 lines 1 and 2 the Examiner argues that in BERGENS et al. the first spring as it expands will then compress the second spring.

In the operation of BERGENS et al, as best can be understood, applicant believes that spring 156 will be compressed as the syringe 120 reaches its forward position (see column 13 lines 4 to 9), to release the injection head 142 to land on the syringe plunger 126. However, most importantly, there is no suggestion in BERGENS of an arrangement in which '*…the first spring, as it fully expands, will then compress [i.e. cause contraction of] the second spring to urge the plunger forward and thereby…expel a dose…*'. In BERGENS et al spring 156 has already been compressed when plunger movement starts, and there is no indication or reason why it should be further compressed during plunger injection movement.

The passages from BERGENS et al. on pages 5 and 6, numbered 2 to 9, cited by the Examiner are, Appellant respectfully submits, quoted out of context. Specifically, the arrangement of Figures 1A to 1D cited by the Examiner makes no reference whatsoever to damping during the autoinjection movement. Instead, damping during the autoinjection movement appears to be explicitly described as a feature of the

embodiments of Figures 2, 3 and 4. Thus comments 2 to 5 appear to be relevant only to these later embodiments rather than the embodiment referred to by the Examiner in Figure 1. In any event, they do not disclose the features as claimed.

On page 10, in response to the Examiner's comments on lines 1 to 7, we note that BERGENS et al. disclose that the plunger guide 153 (acted upon by the injection head 142) continues forward movement against a weaker force of the damping spring 156 during the penetration stage. There is no disclosure of the state of the spring after the penetration stage, as to whether the spring remains compressed or re-expands. Even if the spring 156 remains compressed, it is not (further) compressed (i.e. shortened) by expansion of the first drive spring 142 when the plunger 126 is moved forwardly.

Response to Arguments (page 7, line 8 onwards)

1. Appellant respectfully points out that the inventor, Jeremy Marshall, is a highly experienced inventor named on over 30 U.S. patents in this field and, despite spending hours trying to discern the operation of BERGENS et al., has been unable to identify the nature of the assembly of the syringe plunger guide 153 and the syringe plunger part 151. The description of these components appears to be particularly opaque and neither the US attorneys of record, nor the instructing European patent attorney, with over 80 years combined experience, have been unable to identify precisely how BERGENS et al. functions. All

that can be said with certainty is that the drive spring 141 acts on the injector head 142 which itself acts on the penetration head assembly 150 made up of the syringe plunger guide 153 and the syringe plunger part 151 that are urged apart by spring 156. As has been apparent during prosecution, the position of spring 156, its action and the manner in which syringe plunger guide 153 and syringe plunger part 151 is inadequately described for an enabling disclosure and even upon exhaustive forensic-like study the precise operation cannot be discerned.

The above observation can be resubmitted in the form of a Declaration if the Office believes it will be more probative in that form.

2. The Examiner is inconsistent here as, earlier in the Answer, he equates the plunger of Claim 1 with item 126 of BERGENS et al. Nevertheless, this interpretation of BERGENS et al. does not read onto Claim 1 because the second spring has to act '*…in compression between said plunger and the syringe and in opposition to said first spring when the plunger presses said piston forwards to eject the dose…*'. Moreover, the second spring 156 acts between the syringe plunger guide 153 and the syringe plunger part 151 and not between the syringe plunger 126 and the syringe 120.

On page 8 lines 7 to 11 the Examiner refers to the plunger as being item 126 rather than 142 as above.

Again, the spring 156 acts between items 153 and 151. As previously explained, it is impossible for the spring 156 to be located on the central axis of the device because, as is evident from Figure 1C, plunger shaft 126 runs through the centre of the sleeve 151. It is absurd to suggest that spring 156 must act between plunger 126 and 120 simply because they are superimposed in the same view.

Appellant respectfully submits that the interpretation of the phrase '*acting between*' when referring to the second spring needs no explanation; its normal meaning is that it lies in the load path between the syringe and the plunger, and as later defined is compressed (i.e., contracts) during the final extension of the first spring.

In the arrangement of BERGENS et al., the spring 156 acts in the load path between the first spring 141 and the syringe body 120. As soon as the syringe has reached its forwardmost position the penetration head assembly 150 operates to release the injection head 142 so that it acts on the plunger shaft 126 of the syringe. In this, autoinjection phase, the second spring 156 is not in the load path of spring 141 ⇨ injection head 142 ⇨ plunger shaft 126 ⇨ piston 125.

3. The spring 156 urges the plunger guide 153 rearwardly relative to the syringe plunger part 151. Towards the end of the penetration movement, the plunger guide continues forward movement to reveal the tapering surfaces 161 which

compress the legs 143 of the injection head to land on the plunger shaft 126. Note column 12 lines 40 to 46 states that the legs 143 are compressed '*…from an intermediate position…in which the legs act on the plunger guide 153, to a narrow position… in which the legs are free to land on syringe piston 126…*'. This, together with a comparison of the relative positions of the components in Figures 1B and 1C clearly shows that the injection head moves **relative to** the syringe plunger guide 153 and not **with** the syringe plunger guide.

The Examiner argues that BERGENS et al. discloses an arrangement in which, once the syringe reaches its forward position, the first spring compresses the second spring to urge the plunger forward to expel a dose…. Upon careful review of the Examiner's arguments in support of this stance, we do not believe that this supports his conclusion. Claim 1 requires '*…the first spring, as it fully expands, will then compress the second spring to urge the plunger forward…*'. As above the ordinary plain meaning of this phrase is that as the first spring expands this is accompanied by compression (contraction) of the second spring and forward movement of the plunger. The phrase '*…compress the second spring to urge the plunger forward…*' clearly requires the second spring to contract. The *Merriam-Webster Dictionary* gives the transitive meaning of '*to press or squeeze together*' and '*to reduce in size, quantity or volume as if by squeezing*'. The notion therefore that the spring 142 of BERGENS et al., as it

fully expands, will then compress the second spring 156 to urge the plunger forward is flawed because, as previously explained, for BERGENS et al. to operate as required, the spring 156 will have reached its full extent of compression by the time the injector head legs 143 are released from the slots in the syringe plunger guide 153. By this action the injector head 142 is effectively uncoupled from the penetration head assembly and instead transfers its thrust to the plunger shaft 126.

Conclusion

It is believed that the foregoing discussion underscores the impropriety of the rejection remaining on appeal and supports the showing made in Appellant's main brief that this rejection should be reversed. Such action is accordingly respectfully requested.

Respectfully submitted,

YOUNG & THOMPSON

/Robert E. Goozner/

Robert E. Goozner, Reg. No. 42,593
Attorney for Appellant
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573

REG/fb

March 12, 2010